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> Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Pkwy. College Park, MD 20740

RE: Notification of statements on a dietary supplement known as, St. John's Complex<sup>™</sup>

October 9, 2003

Dear Ladies/Gentlemen;

Pursuant of 21 C.F.R. Subpart F, section 101.93, Body Wise International, Inc. ("Body Wise" the distributor, which is located at 2802 Dow Avenue, Tustin, CA 92780) wishes to notify the Food and Drug Administration that it has commenced marketing a dietary supplement known as St. John's Complex™ which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as St. John's Complex™.

- St. John's Complex™ St. John's wort-nature's feel-good herb.
- St. John's Complex™ may help support positive emotional balance. St. John's wort may play a role in the regulation of serotonin, a neurotransmitter important for normal mood, sleep, memory, and learning. This herb is combined with chamomile and passion flower, which help support a calm mood.
- St. John's Wort Known as "nature's feel-good herb," St. John's Wort has been used since the Middle Ages to promote relaxation. Helps to support a healthy mental outlook.
- Chamomile Best known for its sedative properties. Generally regarded as one of the safest herbs available.
- Passion Flower May help promote healthy sleep.
- St. John's Complex™ supports a healthy mood. (Addressed by the ingredients: St. John's Wort Flower Extract, Chamomile Flowers, and Passion Flower Leaf.)

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The above statements are accompanied by the required disclaimer, which is prominently displayed in a box in boldfaced type.

The information contained in this notice is complete and accurate. Body Wise maintains on file substantiation that these statements are truthful and non-misleading.

An original and two copies of this notification are being submitted.

Sincerely,

Alan E. Huffington

Director of Regulatory Affairs

dw/aeh

Enclosures: Two copies of this two-page letter.